Remarks

Restriction Requirement under 35 USC §121

The Applicants herein affirm their oral provisional election with traverse.

Particularly the Applicants respectfully point out to the Examiner that **the invention is a diagnostic device as well as a method for detecting and distinguishing the presence of, 38 different subtypes of human papilloma virus, for example, simultaneously.** If the diagnostic device were necessarily limited in its ability to merely distinguish two papilloma viruses at time - a patient at risk for cervical cancer, for example, would require 38^2 or 1,444 tests. This is *precisely the advantage of the current invention*. The Applicants therefore respectfully submit that restriction to two oligonucleotides specific for human papilloma virus is improper under 35 USC §121 in view of the invention subject matter as a whole.

All of the oligonucleotides set forth in the Markush group of claim 1 are specific for human papilloma virus.[1] Accordingly, a single search is required to evaluate the novelty of the subject matter. Moreover, the Applicants do not claim these oligonucleotides, *per se*. They are *merely reagents* for employment in the claimed device.

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[1] The Applicants have particularly pointed out and described distinct oligonucleotide reagents for employment in the device, wherein each oligonucleotide is specific for one human papilloma virus subtype. These reagents are tabulated into 38 groups at pages 6-25 of the specification. The applicants respectfully point out that claim 1 is now drawn toward a device which *comprises* a first oligonucleotide corresponding to a first subtype of human papilloma virus and a second oligonucleotide corresponding to a second subtype of human papilloma virus. The Applicants respectfully submit that, in view of the claims now submitted and the written description at pages 6-25 of the specification, the diagnostic device, reagents, and methods related thereto are clearly defined and supported by the specification.

The Applicants respectfully submit that a "serious burden" does not exist on the Examiner to examine the claims now submitted.[2] The examiner is also respectfully referred to §803.04 of the Manual of Patent Examining Procedure (MPEP) Edition 8, August, 2001. The Applicants respectfully request the Examiner to withdrawal the restriction requirement.

Foreign Priority

The Applicants respectfully defer the submission of a certified translation of their priority application under 35 USC §119(b) until prospective allowance of the claims.[3]

Minor Informalities

The Applicants have corrected the informalities objected to by the Examiner at page 4 of the Official Action by amendment to the specification. The amendments to the specification are presented herewith.

Claim Rejections

The Examiner has rejected Claims 1-13 under 35 U.S.C. §112, second paragraph.

At the outset, please note that Claims 4 and 6-12 have been canceled. The Applicants have amended claim 1 as recommended by the Examiner. Claim 5 now depends from claim 1. Claim 13 has been amended as recommended by the Examiner.

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[2] Criteria for restriction between patentably distinct inventions. MPEP, Edition 8, August, 2001 §803(B).

[3] Applicants respectfully submit that under 37 C.F.R. 1.55(4), a certified English language translation of a non-English language foreign priority application is not required except when, for example, the application is involved in an interference or when necessary to overcome the date of a reference relied upon by the Examiner.

Nucleic acid sequences, each identified by their sequence identifiers (SEQ ID NO), have now been inserted as proper Markush groups in claims 1 and 13. Each SEQ ID NO in claim 13 corresponds to the nucleic acid previously identified by HPV subtype, Accession number, and loci. Applicants therefore respectfully submit that the nucleic acid sequences do not constitute new matter because the original Claim 13, as filed, referred to the same sequences using the NCBI Accession Numbers of the sequences (e.g., www.ncbi.nih.gov) each of which was published at the time of the invention. Accordingly, the Applicants hereby state that under 37 C.F.R. §1.821(g) the information filed herewith in support of claim 13 is not new matter.

Accordingly, the Applicants respectfully request, in view of the claims now presented, that the Examiner withdrawal the rejections under 35 U.S.C. §112, second paragraph.

The Examiner has rejected Claims 1, 2, 5 and 13 under 35 U.S.C. §102(b) as allegedly anticipated by Van Doorn et al. (PCT/EP98/05829).

The Examiner asserts that Van Doorn et al. teach methods and probes for detecting specific HPV subtypes which meet the limitations of Claims 1, 2, 5 and 13.

The Applicants respectfully submit that Van Doorn et al. do not disclose any of the oligonucleotides within either of the Markush groups of claims 1 or 13.[4] Since the Applicants'

[4] Further, Van Doorn et al. teach probes derived from the D region whereas oligonucleotide reagents disclosed and required by the Applicants are all derived from an entirely different L1 gene region of the human papilloma virus. Van Doorn et al. teach probes capable of hybridization with the D region of more than one HPV type (page 4, lines 17-24). In contrast, each oligonucleotide recited within the Markush groups of claims 1 and 13 is specific for a single human papilloma virus subtype. The instant invention provides for the

invention as claimed requires and is limited to the employment of specific oligonucleotide reagents selected from these Markush groups - and - Van Doorn does not disclose *any* of these specific oligonucleotides, Van Doorn et al. do not anticipate the subject matter of the invention as now claimed.[5]

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) and Van Doorn et al. be withdrawn.

The Examiner has rejected Claim 3 under §103(a) as allegedly unpatentable over Van Doorn et al. in view of Southern et al. (U.S. Patent No. 5,700,637). The Examiner has also rejected Claims 5 and 13 under 35 U.S.C. §103(a) as allegedly unpatentable over Van Doorn et al. in view of Bauer et al. (U.S. Patent No. 5,639,871) and in further view of Orth (U.S. Patent No. 5,981,173).

Van Doorn et al. do not teach or suggest any of the oligonucleotides recited in either of the Markush groups required by claims 1 or 13. Claims 3 and 5 both depend from claim 1 and require the same reagents as claim 1. Since none of the references cited by the Examiner disclose, contemplate, teach, or suggest *any* of the oligonucleotides now required by the claims, 3, 5 and 13 - even if the references are combined - none supply a critical element of the invention, namely the distinct oligonucleotide species, each of which is specific for a single human papilloma virus subtype. These specific

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simultaneous detection and identification of HPV subtypes contained in a single sample.

[5] A rejection under 35 U.S.C. §102(b) is proper when the cited reference identically discloses the subject matter of the invention as claimed. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1990).

oligonucleotides *precisely provide the advantage of the current invention*.

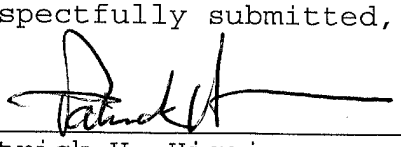
Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §103(a) be withdrawn.

* * *

For all the foregoing reasons, the Applicants submit that Claims 1-3, 5,and 13-19 are in condition for allowance. Early action toward this end is courteously solicited. The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution.

The Commissioner is authorized to charge any deficiency or credit any overpayment in connection herewith to Deposit Account No. 13-2165.

Respectfully submitted,



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Enclosures: Appendix A
Sequence Listing

Appendix A

In the Specification:

Please insert at page 1, line 1 the following paragraph:

This application claims priority under 35 U.S.C. §119(b) to Taiwan Patent Application No. 90110785 filed April 5, 2001, the entire disclosure of which is incorporated by reference herein.

(Page 25, line 5) Each dot on the carrier 11 is an oligonucleotide selected from Tables 1 to 36. For example, an oligonucleotide on the carrier 11 could be selected from one of the sequences numbered [M1101 to M1124] SEQ ID NO: 1 to SEQ ID NO 24(shown in Table 1) for identifying the subtype 11 of human papilloma viruses (HPV 11).

(Page 25, line 9) The method for mounting the oligonucleotides on the carrier 11 (the nylon membrane) is described as follows.

1.-TTTTTTTTTTTTTT (SEQ ID NO: 647) is added to the 3' end of the oligonucleotide provided by the present invention by terminal transferase according to the following steps 1.1 to 1.3.

(Page 26, line 15) Each dot on the carrier 21 is an oligonucleotide selected from Tables 1 to 36. For example, an oligonucleotide on the carrier 21 could be selected from one of the sequences numbered [M1101 to M1124] SEQ ID NO: 1 to SEQ ID NO: 24 (shown in Table 1) for identifying the subtype 11 of human papilloma viruses (HPV 11).

(Page 28, line 5) 2.1 Glutaldehyde-3-phosphodehydrogenase gene is used as the internal control of the polymerase chain reactions according to the following steps 2.1.1 to 2.1.3.

2.1.1 Mixing the following components:

Reagent	Stock	amount	Final concentration
Sterile H_2O		2.6	
10X *Taq* Buffer		0.5	1X *Taq* Buffer

dNTP	2.5 mM	0.4	200 μM
Template		1	
GAP241-5[1)] primer	10 pmol/μl	0.2	0.4 pmol/μl
GAP241-3[2)] primer	10 pmol/μl	0.2	0.4 pmol/μl
ProTaq (PROTECH)	5 U/μl	0.1	0.1 U/μl
Total volume (μl)		5	

1) Gap21-5 (SEQ ID NO: 648): CCACCAACTGCTTAGCACCCC

2) Gap21-3 (SEQ ID NO: 649): TGCAGCGTACTCCCCACATCA

3) The proper amount of mineral oil is added to prevent the evaporation.

(Page 28, line 11) 2.1.2 The polymerase chain reaction is performed according to the following programs.

Program 1	Program 2	Program 3
	94°C , 15[秒]seconds	
94°C ,	57°C ,	72°C ,
3 minutes	1 minute	5 minutes
	72°C , 30 seconds	
	40 cycles	

(Page 29, line 8) 2.2.2 The polymerase chain reaction is performed according to the following programs.

Program 1	Program 2	Program 3
	94°C , 15[秒]seconds	
94°C ,	45°C ,	72°C ,

3 minutes	1 minute	5 minutes
	72°C ,	
	1.5 minutes	
	45 cycles	

(Page 32, line 22) The subtype of human papilloma viruses identified by each dot of the dot array 32 is illustrated in Fig. 3(b). SC (system control) presents the PCR product amplified from any subtype of human papilloma viruses and biotin-contained primer. NC (negative control) presents the plants DNA fragment irrelevant to HPV. IN (internal control) presents the sequence 5'-gcccagactgtgggtggcag-3' (SEQ ID NO: 650) of the housekeeping gene, Glyceraldehyde-3-Phosphate Dehydrogenase (GAP-DH).

In the Claims:

1. (Amended) A detector for simultaneously detecting and identifying at least one subtype[s] of human papilloma virus[es] (HPV) contained in a sample selected from the group consisting of (HPV 6, HPV 11, HPV 16, HPV 18, HPV 26, HPV 31, HPV 32, HPV 33, HPV 35, HPV 37, HPV 39, HPV 42, HPV 43, HPV 44, HPV 45, HPV 51, HPV 52, HPV 53, HPV 54, HPV 56, HPV 58, HPV 59, HPV 61, HPV 62, HPV 66, HPV 67, HPV 68, HPV 69, HPV 70, HPV 72, HPV 74, HPV 82, HPV CP8061, HPV CP8034, HPV L1AE5, HPV MM4, HPV MM7 and HPV MM8), comprising:

a) a carrier [having] comprising a first part and a second part for carrying said sample thereon;

b) a first oligonucleotide corresponding to a deoxyribonucleic acid contained in a first subtype of human papilloma virus carried on said first part of said carrier; and

c) a second oligonucleotide corresponding to a deoxyribonucleic acid contained in a second subtype of human papilloma virus carried on said second part of said carrier,

wherein said first and second oligonucleotides are each selected from the group consisting of: [respectively hybridized with deoxyribonucleic acids contained in a first subtype of human papilloma virus and a second subtype of human papilloma virus for simultaneously detecting and identifying subtypes of human papilloma viruses.] (SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, SEQ ID NO: 41, SEQ ID NO: 42, SEQ ID NO: 43, SEQ ID NO: 44, SEQ ID NO: 45, SEQ ID NO: 46, SEQ ID NO: 47, SEQ ID NO: 48, SEQ ID NO: 49, SEQ ID NO: 50, SEQ ID NO: 51, SEQ ID NO: 52, SEQ ID NO: 53, SEQ ID NO: 54, SEQ ID NO: 55, SEQ ID NO: 56, SEQ ID NO: 57, SEQ ID NO: 58, SEQ ID NO: 59, SEQ ID NO: 60, SEQ ID NO: 61, SEQ ID NO: 62, SEQ ID NO: 63, SEQ ID NO: 64, SEQ ID NO: 65, SEQ ID NO: 66, SEQ ID NO: 67, SEQ ID NO: 68, SEQ ID NO: 69, SEQ ID NO: 70, SEQ ID NO: 71, SEQ ID NO: 72, SEQ ID NO: 73, SEQ ID NO: 74, SEQ ID NO: 75, SEQ ID NO: 76, SEQ ID NO: 77, SEQ ID NO: 78, SEQ ID NO: 79, SEQ ID NO: 80, SEQ ID NO: 81, SEQ ID NO: 82, SEQ ID NO: 83, SEQ ID NO: 84, SEQ ID NO: 85, SEQ ID NO: 86, SEQ ID NO: 87, SEQ ID NO: 88, SEQ ID NO: 89, SEQ ID NO: 90, SEQ ID NO: 91, SEQ ID NO: 92, SEQ ID NO: 93, SEQ ID NO: 94, SEQ ID NO: 95, SEQ ID NO: 96, SEQ ID NO: 97, SEQ ID NO: 98, SEQ ID NO: 99, SEQ ID NO: 100, SEQ ID NO: 101, SEQ ID NO: 102, SEQ ID NO: 103, SEQ ID NO: 104, SEQ ID NO: 105, SEQ ID NO: 106, SEQ ID NO: 107, SEQ ID NO: 108, SEQ ID NO: 109, SEQ ID NO: 110, SEQ ID NO: 111, SEQ ID NO: 112, SEQ ID NO: 113, SEQ ID NO: 114,

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SEQ ID NO: 640, SEQ ID NO: 641, SEQ ID NO: 642, SEQ ID NO: 643, SEQ ID NO: 644, SEQ ID NO: 645, and SEQ ID NO: 646), or a complementary sequence thereof.

5. (Amended) The detector according to claim [4] 1, wherein said detector is an oligonucleotide chip.

13. (Amended) A method for detecting a subtype of human papilloma virus[es] DNA contained in a sample, comprising the steps of:

a) providing an oligonucleotide [complementary to a sequence specific to said subtype of human papilloma viruses] about 15 to about 30 bases in length, that is complementary to a DNA sequence selected from the group consisting of (SEQ ID NO: 651, SEQ ID NO: 652, SEQ ID NO: 653, SEQ ID NO: 654, SEQ ID NO: 655, SEQ ID NO: 656, SEQ ID NO: 657, SEQ ID NO: 658, SEQ ID NO: 659, SEQ ID NO: 660, SEQ ID NO: 661, SEQ ID NO: 662, SEQ ID NO: 663, SEQ ID NO: 664, SEQ ID NO: 665, SEQ ID NO: 666, SEQ ID NO: 667, SEQ ID NO: 668, SEQ ID NO: 669, SEQ ID NO: 670, SEQ ID NO: 671, SEQ ID NO: 672, SEQ ID NO: 673, SEQ ID NO: 674, SEQ ID NO: 675, SEQ ID NO: 676, SEQ ID NO: 677, SEQ ID NO: 678, SEQ ID NO: 679, SEQ ID NO: 680, SEQ ID NO: 681, SEQ ID NO: 682, SEQ ID NO: 683, SEQ ID NO: 684, SEQ ID NO: 685, SEQ ID NO: 686, SEQ ID NO: 687, and SEQ ID NO: 688) or a complementary sequence thereof;

b) hybridizing said oligonucleotide with the [deoxyribonucleic acid (DNA)] DNA contained in said sample;

c) removing non-hybridized DNA contained in said sample; and

d) detecting [hybridized DNA to show whether said subtype of human papilloma viruses contained in said sample,] a hybridization complex formed between said oligonucleotide and said DNA as indicative of the presence of said subtype of human papilloma virus contained in said sample. [wherein said sequence

specific to said subtype of human papilloma viruses is selected from following

HPV subtype	Accession number/bp	loci /bp
HPV 11	NC 001525/7931	6727 - 7135/409
		1044 - 1509/466
HPV 16	NC 001526/7904	6602 - 7013/412
		1089 - 1538/450
HPV 18	NC 001357/7857	6578 - 6992/415
		1135 - 1609/475
HPV 26	NC 001583/7855	6553 - 6967/415
		1093 - 1522/430
HPV 31	NC 001527/7912	6520 - 6931/412
		1083 - 1476/394
HPV 32	NC 001586/7961	6837 - 7245/409
		1032 - 1536/505
HPV 33	NC 001528/7909	6559 - 6967/409
		1100 - 1532/433
HPV 35	NC 001529/7851	6542 - 6953/412
		1089 - 1497/409
HPV 37	NC 001687/7421	6711 - 7125/415
HPV 39	NC 001535/7833	6605 - 7019/415
		1149 - 1593/445
HPV 42	NC 001534/7917	6802-7210/409
		1085-1485/401
HPV 43	U12504/455	21-435/415
HPV 44	NC 001689/7833	6647 - 7061/415
		1038 - 1491/454
HPV 45	NC 001590/7858	6582 - 6996/415
		1136 - 1567/432
HPV 51	NC 001533/7808	6486 - 6897/412
		1092 - 1506/415
HPV 52	NC 001592/7942	6623 - 7031/409
		1085 - 1526/442
HPV 53	NC 001593/7856	6614 - 7022/409
HPV 54	NC 001676/7759	6561 - 6972/412
		1013 - 1484/472
HPV 56	NC 001594/7844	6559 - 6967/409
HPV 58	NC 001443/7824	6608 - 7016/409
		1104 - 1536/433
HPV 59	NC 001635/7896	6571 - 6985/415
		1093 - 1528/436
HPV 61	NC 001694/7989	6732 - 7146/415
		1005 - 1515/511
HPV 62	U12499/449	21 - 429/409
HPV 66	NC 001695/7824	6609 - 7017/409
		1023 - 1545/523
HPV 67	D21208/7801	6584 - 6992/409
		1096 - 1504/409
HPV 68	M73258/6042	2582 - 2996/415

		4990 - 5350/361
HPV 69	NC 002171/7700	6509 - 6923/415
		1101 - 1518/418
HPV 6	NC 000904/8012	6743 - 7151/409
		1045 - 1510/466
HPV 70	NC 001711/7905	6549 - 6963/415
		1149 - 1608/460
HPV 72	X94164/7988	6758 - 7172/415
HPV 74	U40822/3891	1613 - 2027/415
HPV 82	AB027021/7871	6536 - 6950/415
		1094 - 1532/439
HPV CP8061	U12479/452	21 - 432/412
HPV CP8304	U12480/452	21 - 432/412
HPV L1AE5	AF039910/364	11 - 360/350
HPV MM4	U12488/455	21 - 435/415
HPV MM7	U12489/452	21 - 432/412
HPV MM8	U12490/452	21 - 432/412]

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